TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
BIO MEETING)
)

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IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:

STAKEHOLDERS MEETINGS)
BIO MEETING)
)

Room 1A-001
Federal Drug Administration
5100 Paint Branch Parkway
College Park, Maryland

Wednesday,
February 25, 2004

The parties met, pursuant to the notice, at 8:13 a.m.

BEFORE: MS. CINDY SMITH

APPEARANCES:

For United States Department of Agriculture, Animal Plant Health Inspection Service, Biotechnology Regulatory Services:

REBECCA BECH, Associate Deputy Administrator
SUSAN KOEHLER
JOHN TURNER
NEIL HOFFMAN

For Biotechnology Industry Organization:

BARBARA P. GLENN, Ph.D.
MICHAEL J. PHILLIPS, Ph.D.

For Arent Fox:

STANLEY H. ABRAMSON, Esquire

APPEARANCES CONTINUED:

For Syngenta:

DIANA FELNER, Manager, Governmental Relations

For Ventria Bioscience:

STACEY R. ROBERTS, Director of Field Production

For Turner Strategies:

MICHAEL MCGILL, Senior Project Director

For Monsanto:

RUSSELL P. SCHNEIDER, Ph.D., Director

For DuPont:

QUENTIN KUBICEK

P R O C E E D I N G S

(8:13 a.m.)

MS. SMITH: Good morning and welcome. Welcome to our stakeholder discussion series on our upcoming environmental impact statement, or EIS, and our revised plant biotech regulation.

We want to thank you for taking time from your busy schedules to participate in this meeting and share your thoughts with us.

The purpose of these briefings is twofold. First, to share information with you on our plans to move forward, to develop and EIS, as well as our new plant biotech regulations, revising our regulations. And secondly, to gather diverse and informative input which will support thoughtful and effective decision-making on our part in the development of our revised regulations.

We have here, from BRS, most of our management team, as well as a number of other staff, and when available, other key agency personnel involved in supporting BRS will be joining us from time to time, as well.

I should mention two key individuals who have now been dedicated to providing full-time management of our work to complete both the environmental impact statement and the revising of our regulations.

John Turner, who you likely know, a very important

member of our leadership team here in BRS. I'm sure you've worked closely with John in the past. I'm very pleased to say that John is leading this effort, providing the leadership for this effort on a full-time basis.

And the second individual, a new face which you may not have met yet, Michael Wach. Michael is a recent hire in BRS as an environmental protection specialist within our Environmental and Ecological Analysis Unit. In addition to possessing a Ph.D. and an environmental law degree, Michael brings research experience in plant pathology and weed science, as well as a number of years of legal experience working on legal cases involving NEPA, the Clean Air Act, the Clean Water Act, and other environmental statutes.

I should also mention, for Barb's benefit and others here, that one of the things that a recent realignment of functions we have done as well is that Rebecca Bech, our associate deputy administrator, will be leading the effort to determine what our role and regulations will be for transgenic animals, insects, and animal disease agents, as well.

As you likely know, we recently participated in interagency discussions with the FDA, the EPA, and the White House which, while concluding that the coordinated framework provides an appropriate science- and risk-based regulatory

approach for biotechnology, that the Plant Protection Act of 2000 provides a unique opportunity for APHIS to revise its regulations, expand our authority, while leveraging the experience gained through the history of our regulation, to enhance our regulatory framework, and particularly positioning us well for the future advancement of this technology.

We also concluded those discussions with a general agreement on how our biotechnology regulatory approach will evolve. Still, there is much opportunity to flesh out the particular details of our regulatory enhancements. Given this, what we would like to do in these meetings is to have an opportunity to hear your thoughts, as well as have an informal give and take of ideas.

We have a unique opportunity to have this kind of discussion, since we are not in a formal rule-making process as of yet. So we are free to speak openly, and exchange ideas with stakeholders and the public.

Our discussion will be professionally transcribed primarily for two reasons. The first is have a precise record of our discussion will provide us a mechanism to go back and refer, and fully consider the input that you are about to provide us.

And secondly, in the interest of transparency and fairness to all stakeholders, this will provide a record of

all of these discussions, so that all stakeholders and the public have the opportunity to have benefit of the discussion of each of the sessions that we're holding this week.

Of course, I should emphasize that while we are happy to share what our current thinking is in terms of the direction that we are considering in BRS for our environmental impact statement and our new regulations, it's important to note that this is just the beginning of a public process, and that we are very open to stakeholder and public input through this process. So you can expect our thinking to evolve throughout the process.

In addition, other officials at USDA, the Administrator, the Undersecretary, the General Counsel, and of course the Secretary, can be expected to provide insightful direction to us as we go through this process, as well.

So while we value all input, it is important for us to recognize that our thinking will likely evolve. So while we may have an enthusiastic discussion today on a particular aspect of our regulatory revisions, this will be an evolving thinking process.

Finally, since it will be hard to predict what the final regulation will look like, which will emerge from this process, I would like to briefly share with you our overall

BRS priority areas of emphasis, which we used to set guidance and direction for our policy and our regulation strategies and operations.

The first is rigorous regulation. Rigorous regulation, which thoroughly and appropriately evaluates and ensures safety, and is supported by strong compliance and enforcement.

Transparency of the regulatory process and regulatory decision-making to stakeholders and the public. We believe transparency is critical to public confidence.

A scientific-based system, ensuring the best science is used to support regulatory decision-making to assure safety.

Communication, coordination, and collaboration with the full range of stakeholders.

And finally, international leadership. Ensuring that international biotechnology standards are science-based, supporting international regulatory capacity-building, and considering international implications of policy and regulatory decisions.

As we prepare to begin our discussion, I will let everyone know that for effective transcription of our session, that all statements and questions need to be directed into a microphone. And for those who have not previously spoken to the transcriber, the first time you

speak we're asking you to identify yourself by name.

With that, I would like to open the floor to hear your comments and whatever discussion that you'd like to bring to this forum.

MR. PHILLIPS: This is Mike Phillips. I'm with the Biotechnology Industry Organization. And Cindy, on behalf of BIO, we, first of all, commend you all for holding these meetings. We think this is very vital. As we go into what we consider to be very important changes that can affect our industry and affect our whole food chain, as we go forward.

And so to have the opportunity in a public setting to come and meet with you and to be able to exchange some ideas, to ask some questions about what your thinking is in this regard, is very commendable. And we support this entirely.

The second thing I would just like to point out is that BIO also supports APHIS in conducting this environmental impact statement going forward. We think this is very critical to this emerging technology as it is maturing. It is time that we have such a programmatic environmental assessment done, and we support it entirely, as well as the potential changes, or the changes that you're considering that you've indicated in Federal Register Notice, along the lines of changes to importation, changes

to interstate movement, the environmental release of certain genetically-engineered organisms, especially in light of the fact that you have, under the Plant Protection Act of 2000 now, much larger authority. This all comes under the heading of this is a good time to be doing this. And again, we as an industry support this in its entirety.

We also support the public comments that you have made, and officials at USDA have made, and you have reiterated in your introductory comments today about your strategy and considerations as you're going forward, in terms of rigorous regulations, tough enforcement. We are extremely supportive of that being done in a very transparent way. Again, it's something that we applaud the agency on.

Also, this whole area of any type of changes that are being considered, that they be grounded in science, and that they be risk-based. These are the cornerstones of what we've come as an industry to expect in the past, and this is what we expect in terms as we go forward. This is extremely fundamental to our industry. And again, this is something that we applaud the agency for continuing.

And this whole area of communicating and coordinating and collaborating with all stakeholders again is something that we certainly try to do. And as our industry is going forward, it's great to see government

agencies having the same attitude.

And the fact that there is always an international implication no matter what we do, in terms of the U.S. and many international forums, the United States is looked to for leadership. And to have that on your radar screen and in your thinking as we're going forward is critical. Because so much of what we're doing here in the United States as leaders in this technology, we are looked to around the world, then, to provide leadership in various international forums in helping develop international standards. And so this is something again that we are very supportive of and applaud you for doing.

In terms of our discussion today, many of the things that we would like to enter into our discussion with you relate, I guess, more around what's in the Federal Register Notice, the types of questions that you're asking, and to be sure that we're interpreting questions in the way in which you intend them to be interpreted. So that when we do provide you our position in another 30 days, that we're on the same wavelength of understanding what it is.

To sort of just kick that off, what we would like to do is, I guess, maybe to first talk a little bit about some of the nomenclature change that you put forward here. As we look to the various parts of 340, that in many cases findings would be subject to some sort of permit. And here

we're assuming this is experimental, as well as commercial, and we'll want to go into some more depth in there with you. But just to get a better feel and be sure that we're interpreting this correctly from our vantage point, of understanding the way the system is today, in terms of notification, in terms of standard permit, and then a non-regulated status. And looking at the nomenclature that you're talking about in the FR, what you consider to be an expedited review permit, is something that we would first provide you with what would have been under notification in the past. Unless the standard permit that you're talking about would still be what we consider to be the standard permit today, when needed.

And then what we would consider to be non-regulated status that we've always been able to apply for --

(Interruption.)

MR. PHILLIPS: The non-regulated status is the third category that we've always looked to in terms of going to commercialization. That being equated with what you would call a commercial permit. Are we interpreting this correctly? Is that the way in which you're sort of envisioning this? Versus where we are today, versus where you think we're going to go. Do those categories sort of get matched up? And I'd be happy to go back over any one of those.

MS. SMITH: I'll start with an answer, and then I'll let you challenge or correct me.

Essentially what we're talking about is moving to a multi-tiered -- in which anything that comes under review, where they historically have either come in through a permit or else meet the criteria for a notification, and all of those items would fall within the permit system. And what we would look at is different levels of permits.

And so based on the risk associated with a category of a certain permit area, then that would determine what the level of review is for that specific crop or trade that came in to us.

So on the permit side, we're envisioning everything from field testing, we're envisioning everything to receive a permit, that there will be different levels of permits based on risk and science.

On the other side, in terms of what we have historically looked at as a deregulation process, I believe we have some language in the Federal Register Notice to suggest that our intention is to build additional flexibility into that deregulation process. So our terminology there, we've not come to any conclusion in terms of what that terminology will look like. But to reflect that that system is evolving and will have additional flexibilities built in, our language will likely change.

And I think in the Federal Register Notice we may have referred to it as improved, and they use approval in the same way as we're using deregulation.

So we're not sure what the final terminology will be for that process, but that is likely to evolve. That will be very similar to deregulation, and the majority of things that will come through the deregulation process will meet the same process in terms of meeting safety criteria and moving out from the regulatory scope, and be deregulated. But we do want to build in some flexibility, so at least some things that could be improved, let's say with conditions or -- we're getting ahead of ourselves.

So the fundamental language changed, and I think is moving from permit notification to permit. And within the permit we would have different classes. Some of those classes would receive an expedited review based on the safety associated with that class.

And then on the other side, in terms of moving more to moving things out of the regulatory system, we are looking at moving from deregulation towards perhaps some kind of an approval terminology. But we've not made any final conclusions on that, yet.

Do you have anything to add?

MR. TURNER: I think Cindy covered it so thoroughly, there's not a whole lot that we can add. With

respect to field testing, the notification system has worked well. And as you look at the changes, there are substantive changes, and there are other changes that are nomenclature. So I think Cindy clearly indicated there will still be classes where we can keep everything that worked about notification. But to get rid of the misconception that's out there now that there are certain things you don't need a permit, you just have to notify the agency, when in fact, you know, we do have significant oversight, and we would like nomenclature that suggests that reality of that system.

Approvals for the vast majority of things where there are no risks, it should function what ideas -- it would be a large category that essentially has deregulation.

MR. PHILLIPS: And whether that would be called a commercial permit or approval, I mean, that's something that you're still giving some thought to. Is that correct?

MS. SMITH: At this point we're not really looking at calling it a permit, on the approval side. We're looking right now more towards approval, maybe approval with conditions, approval for unconfined release, approval without conditions. That's some of the things we're kicking around now.

MR. PHILLIPS: All right.

MS. BECH: When you move to a system like that, one of the things we heard about internationally is some

confusion about what we mean by deregulation. And a lot of the other countries will use the term approval to mean the same thing that we talk about when we say deregulation. So some of our fallout has evolved in the terminology, as well.

MR. PHILLIPS: Well, we've noticed that in the international forum as well. And we would say, on first blush of this, that that makes a lot of sense to us. We get caught up in what we mean by things, and being interpreted differently, we have that not just in the environmental area, but on the food safety side as well, in terms of the way we go about improving things here in the U.S. and what is perceived.

So it will actually help us, both in the international forums, and I think it's, from our vantage point, it will let us have a lot of merit with -- Sam, you may want to follow up with some questions.

MR. ABRAMSON: My name is Sam Abramson.

I think that we've certainly found that some of the terms that are currently in use, while we understand them quite well here in the United States, there is a lot of misunderstanding with our trading partners. And the notion that a determination of non-regulated status somehow means that --, and that APHIS no longer has the ability to regulate that particular organism. Which, of course, is completely false, and is a perception that we do run into.

And it certainly seems like the amendments that you're contemplating would really help to correct those misunderstandings. That's something that's very important to us, as well.

And so, you know, our assumption is that with these approvals, that APHIS's ability to revoke or otherwise review or revisit an approval action would be explicit, so that presumably, based on new information which wasn't available to you at the time that that approval was granted, that our assumption is that it would be clear in the rule or the preamble or both, that such new information would come to your attention. Obviously you would review it, and if you found that it presented a cause for concern, that there would be no question about your ability to revisit that approval action, and if necessary revise it in accordance with new provisions on it, or in rare cases you'd be able to revoke that. And we feel that that's something that you've always had the ability to do. But again, to the extent that that was explicit, we think it would be a very positive step forward.

So if our assumption is correct, and that's helpful to us in being able to formulate our comments on the proposal --

MS. SMITH: Thank you. And I would just confirm that your thinking is correct. And in going through the

process that we've gone through in the recent months in terms of looking at our authority and the potential to change our authority, one of the things that has become clear to us is that it's not been as widely understood that we do have that ability currently, in the current system, to revisit if new information becomes available. And given that that is not well understood, one of our objectives in revising our regulations is to make that much more explicit. We feel like that's a very important aspect of our system, that if it's not well understood, we really need to address that.

MR. ABRAMSON: Just as a follow-up question to that, would it be safe to assume, as well, that you would also make it explicit that, even in the case which we think would be the majority of cases, where an approval was granted without conditions, that there would at least be a condition that the entity receiving the approval would always need a report back to APHIS if information came to their attention which was not previously available, and which suggested that there was some significant adverse effects that might be associated with the organism?

MS. SMITH: That's correct.

MR. ABRAMSON: I'd just also point out that not only is this helpful in our view, in terms of a global understanding of how we address these regulatory issues here

in the United States, but I think it will also be helpful in terms of the process that's going on right now, which I know you're all familiar with, of countries for the first time that are trying to come to terms with the regulation of biotechnology. Typically under the auspices of biosafety protocol.

And I think to the extent that there is a clear path they have by which APHIS was processing these products, I think it would be very helpful for those nations to be able to use that we would hope as a model for their own programs, so that they would, in fact, have all of the same models we laid out in terms of being risk-based, being transparent and so forth. So it has additional benefits in that regard.

MR. PHILLIPS: I think one thing we've been wondering about is, it gets to the enforcement side to emphasize, Cindy, in your opening comments. And if you take the situation in which you do, say, give an approval that has conditions to it, I think, in the way we try to think this through some, we certainly understand that a condition applies exclusively to, many times to permit the holder, or whoever is asking, what entity is asking for the approval. But there are those instances in which it might apply to growers. For example, if you're talking about a condition that is, you put in cyclically, say, on isolation, are there

instances where you would find yourselves, you think, putting enforcement at the grower level? Or would you still view this as looking to the entity that was asking for the approval in the first place?

Have you thought about some of those things?

MS. SMITH: Yes, and we're beginning discussions about that. But that's an area where we're really very open. I think what we have to consider is what the range of, if we're going to consider issuing approvals with conditions, we need to look at what the potential types of conditions might be. And then consider who is in the best position, as well as who has the appropriate responsibility, maybe legally, maybe financially, to enforce those, or make sure that those conditions are complied with.

We do see this as an area that will be seldom needed. And so the majority of the things that come through the system, this won't have to apply. So it's more kind of those few and far between issues that may come up that we may as of yet not even be familiar with. And so what we'll be looking at is trying to consider all those things, and build some flexibility into the system around that. And certainly it's an area where we're very open to discussion and input during the coming months.

Do you have anything else you want to add?

MR. TURNER: We're certainly sensitive to the

argument that if you start putting conditions on it, then it might undermine the idea -- at that point it's very difficult to say this is as safe as -- or monitoring. So again, this would be a separate category. It might allow for some special cases to go forward, not to put conditions on the type of things that were being deregulated now, but to let some special cases go forward into commercialization that would be very difficult for us to perceive now.

So there might be some time-limited conditions, some time to gather extra data, monitoring, if it were tied to a specific unresolved risk, never monitoring just for the sake of monitoring. Those are the types of things that we're considering, considering is the key word, as we go forward.

So it's about flexibility in the way that we look at approvals.

MS. BECH: One of the other things that we consider when looking at flexibility is, to get to your question about the grower and people who are involved at different levels besides just the permit holder, is if there might be something that's going on for a long term, would be use of something like a compliance agreement, where there are certain things that are spelled out that people agree to. But this is all very open, we just begin looking at the use of something like that in association. But the long-

term, you know, more flexibility.

MR. PHILLIPS: You would envision it that at times possible it would be -- so that all growers -- what these particular conditions are? And monitoring how that's progressing, that type of thing? That's one way.

MS. BECH: Yes, yes. Very open, so that everyone understands what the roles are. Yes.

MR. ABRAMSON: The concept of plausibility is something that we think is really critical in any regulations that you might come out with.

I think that looking back on history, regulation of biotechnology, in fact going back to NIH oversight of biotech research, the federal agencies had always found that it was very helpful not to try and impose regulations that were based on today's knowledge, because by the time those guidelines or regulations got into the Federal Register, we already knew more, and we didn't want to be constrained in a way that wasn't consistent with the ultimate technology.

And so I think the agencies over the years have been very, very good about developing regulations that provided for rigorous oversight, but yet gave them the flexibility to adjust to new knowledge as it became available. And we're confident that the amendments that you're contemplating would do the same, whether it's in this particular area of the approvals, or in any other aspects.

I think that it could well be reflective, also, of the risk-based categories in the forum. You're -- some discussion, too. If we were to sit down today and try and figure out what those categories should be based on what we've been looking at since 1986, we'd probably come up with one set of categories. And then if we were to do that exercise five years from now, based on what's coming down the pike, they could look very different.

And so we think it's important not to be so specific that we wind up finding that we have things that don't exactly fit, and then we don't know what to do with them. So the notion of flexibility is something that is, in our view, an important goal in any regulatory process.

I guess we had one additional question about the approvals that would be associated with commercialization. And it sort of deals with the issue of grandfathering of existing determinations that have been made. And this, of course, is very important to us, because we feel that there has been a lot of time and effort and research that's gone into those few products that have ultimately made it through the long product development and experimental research process. And we'd be interested in getting some sense about how you're thinking of dealing with the grandfathering issue. I mean, specifically, if a company had a product for which there was a determination of non-regulated status,

what would that look like after the new regulations are out?

MS. SMITH: Yes, I think that's an important area to clarify. And it would be our intention, because the deregulation process that we've had in has been effective to date, our intention is to grandfather in everything that's been deregulated into the new system, in terms of whatever we evolve to.

The way the new system is evolving is to add additional flexibility, particularly for future products, and to allow us to address future issues. So we don't see any deficiencies in terms of the deregulation process as it has existed, and are very comfortable with those products that have come through the system and completed a full review.

So those products, in our new regulations, we would state that those products are grandfathered in, and that their status will not be affected by the new regulations.

MR. PHILLIPS: And again, I'd like to just emphasize one thing that Stan said. But just to underscore again, I think this idea of flexibility and how important that is for this technology that will continue to evolve long after many of our careers are over with, and to hope and not have something to put into a Federal Register or a hard-core regulation that would put someone in a box, and

not be able to see our technology develop that would have many benefits to society, that is something that is always on our mind. And so flexibility is very critical. And you know that we have confidence that you feel the same way, and that we can all keep an eye toward it.

So if you put policy in place that does ensure health and safety for the environment, but at the same time allows us the freedom to be able to, when things do evolve and change, who to have our policy --

You mentioned, particularly in question six, that APHIS is considering a new mechanism that involves APHIS, the states, and the producer for the production of plants not intended -- would prefer to develop -- pharmaceutical industrial compounds and refinement conditions with governmental oversight.

We're a little unclear as to what you have in mind here when you say a new mechanism including yourselves, the states, and a commercial entity. And I was just wondering if you could provide us with a little bit more of your thinking.

MS. SMITH: Sure, sure. We recognize that in the area of pharmaceutical industrial production, that there will be a number of plants that will not meet the safety criteria to be deregulated.

We also hear loud and clear from a number of the

regulated community that it's not their intent to commercialize pharmaceutical industrial products, absent government oversight. Their preference is to maintain government oversight.

Given that, what we want to do is add another feature of flexibility into the system, where we will develop some kind of a new mechanism -- and this is really an area that is ripe for an exchange of what that might look like -- what we are looking at is, what are the limitations of the current permitting system that we might want to build on, to make enhancements to the system to address what could be potentially long-term conduct of field research, and have that maintained under government oversight. And do it in a way that is more effective in terms of a regulatory approach.

When I say effective, an example I would give is, say, transparency. One issue that we know is that the pharmaceutical industrial field tests, there is much interest from the public and from a number of state groups to understand what kinds of things are being field-tested. While we have limitations in terms of our requirements under confidential business information to restrict that information, we also recognize that that causes somewhat of a dilemma to the public, in terms of understanding and feeling like they can feel confident that the things that

are being field-tested, the crops that are being field-tested, have all the adequate safeguards in place.

So a feature of a new mechanism that we would want to look at, specifically for pharmaceutical industrial field tests, is some new approach to transparency, where we can honor confidential business information, but we can provide the public with increased information about specifically, more specifically what's being field-tested, without violating confidential business information, as well as the safeguards that are in place to ensure consignment of that field test.

So transparency is an issue that we would like to address in this new mechanism.

There's also some efficiency issues that we'd like to address. If the same research or the same field trial is going to be conducted every year for 10 years, if a company is leaving something to commercialization, it doesn't make sense for a brand-new permit to be applied for with the full package of information every year, and for us to do a full review every year.

So what we want to consider is, is there some kind of a more efficient way to provide information, full information, and do a full review initially; and then have the applicant, even prior, to provide us with additional information that they may learn through the course of that

particular field trial, as well as any new information that may become available to them, as well as any changes in their plans for future use. Provide us that new and additional information, and that be a significant part of what we review in the subsequent years.

So the idea is, what kind of a mechanism can we develop that would address some of these issues that are raised by the intention of applicants to essentially conduct the same research year after year, in an area that the public is going to have increased interest in really understanding what's being researched, as well as the safeguards that are in place.

I don't know, John, if you have any more to add.

MR. TURNER: Yes, that's an excellent summary. We're not looking so much, we wouldn't want to give the idea that we're giving a lighter regulatory touch to these things in the pharmaceuticals and industrial. Certainly we'd want to retain government oversight.

But the idea that if they're going into production it's going to become routine, so coming in to get your permit every year, describe the test, come back, and having your number, is that important? Or is it more now agreement on the standard procedures, how you will do all of the harvesting, all of the transport, all of the process, such that we can review those types of things as a package?

Maybe more dependent on audits. There would still be inspections.

But just looking at, is this the most efficient way? Cindy used the term "efficiency" several times. I think that's the key. The most efficient way. Once something goes into a more routine-type production. Whereas our permitting system really was designed for field tests.

MR. PHILLIPS: Right.

MS. SMITH: Another aspect we mentioned in the notice, this new mechanism involving us, the researcher and the states. And that reference to states is very intentional. One of the things that we think is very important is to really partner very directly and thoroughly with the states.

Yesterday I had the opportunity to meet with the commissioners from each of the states' departments of agriculture, and talk about several proposals that we have on the table before, and asked the state departments of agriculture association to work more closely with them. And in fact, one of the things that we're planning to do is have a meeting where each state department of agriculture will come and actually participate with us in the development of the new regulation.

So this is an area that we'll be meeting with them, and talking with them, and making sure that the

states' interests are very much addressed in our revisions to our regulations.

MR. ABRAMSON: In your conversations with the folks at the state level, has that gotten to the point of identifying what role the states might play in this new mechanism?

MS. SMITH: No. At this point we're just talking with the states about the best mechanism for us to get together and gather their input in a very systematic and engaged way with us.

MR. ABRAMSON: If I understand your explanation of this mechanism --

(Interruption.)

MR. ABRAMSON: If I understood your explanation of this, it sounded like, first of all, that this is something that you're thinking of for PMPs and PMIPs.

MS. SMITH: Yes.

MR. ABRAMSON: It also sounded like it would include both the ability to provide for multi-year permits or renewable permits for field tests that go on over an extensive period of time, but then it also contemplated some of these products moving into commercialization. At which point you also wanted to provide a mechanism to address the commercial planning, so the PMPs and PMIPs and what the appropriate oversight would be at that stage, as well. So

it seemed like it covered both, potentially, at least, anyway, field testing as well as commercialization for these products.

And I think that, you know, at first blush it sounds to us like trying to build in the flexibility and address the efficiency issues, makes a lot of sense.

I think the one thing that we're going to have to go back and do some thinking about is whether these concepts appropriately should be confined to PMPs and PMIPs; whether there is really a basis for identifying this one particular category of products and saying that we need some special mechanism here, as opposed to some of the mechanisms that you've been considering just in general, such as the approval process, and the possibility that there would be some subset of approvals and conditions associated with them. It's just something that we're going to have to go back and think about.

But I think that your clarification is very helpful to us, because we weren't exactly sure what question number six was designed for.

MS. SMITH: If I could just clarify. I'm not sure if we've been clear that our intention, essentially, is to have two mechanisms for commercial production, for pharmaceuticals and industrials.

One is that, through the approval process, if the

pharmaceutical or industrial crop can meet the same safety criteria as any other crop, then it would be eligible to be deregulated or approved.

And then this is a second alternative. So if it's not eligible for deregulation, but there's still the intention to move it to the commercialization phase, as well as if there's a choice not to move it through the approval and deregulation phase, that this is a second option that would be available.

But your point is taken about what types of crops this whole second mechanism should be considered for.

MR. ABRAMSON: I think that's an important point. And we've had quite a bit of discussion around that, in terms of hoping that we're being consistent with what we all stated at the front, in our preambles, about wanting a science-based, risk-based approach to how we regulate in this arena.

And when it comes to the sort of three categories of risk that you laid out, in terms of categories based on risk, the first two make a lot of sense to us. But we've had a lot of discussion around the third category, where it institutes PMPs and adjusted products, just in the naming of that puts it into another risk category, where in point of fact you've come up with scenarios of which, you know, you have a protein that's not necessarily going to be hazardous

to cows or the environment.

But we're wondering if what maybe you're driving for is, is there a category that's based on intent. And having that possibly would be even more consistent with a risk category.

MS. SMITH: It's worth noting the second half of how we describe that third item is not intended for food we eat. And I think that's a key aspect of that, that we're considering in that.

And we recognize, too, that there are certainly pharmaceuticals and industrial as they are growing now that don't pose risks. And so within that category, we would have to have some flexibility. It might look like tiers within a tier, or it might look, you know -- we put out these potential tiers as potential tiers to start the dialogue and to engage in discussion.

We have also talked about whether something can start in one tier, and then after evaluation move to another tier, based on safety information that -- evaluation. So this is very much open for discussion.

MR. PHILLIPS: I think one of the issues that I'm sure you are very much aware of from our industry standpoint is that of adventitious presence. And you know, we certainly see, in the questions you're asking and what's being considered in terms of changes to Part 340, it's going

to open up some avenues of how you can address adventitious presence.

But I think, as you also are aware in terms of our public statements in the past which have exchanged, waiting to let this process go forward and looking two years down the road to maybe having an answer to adventitious presence is something that, I think, whether you're in the industry or whether you're in government, it's just not tenable.

We need an answer to adventitious presence today. And we would really like to be able to explore with you what are the ways in which we can get something done in the area of adventitious presence. Because we just consider it to be so fundamental to many of the issues that are not only here in the United States, but what we're facing around the world. And Lord knows, we need a science-based approach to adventitious presence for the international community. We don't have it today.

We're being looked to by many countries around the world as leaders in this technology to come up with it. And we, as an industry, certainly have thought about this a lot, done a lot of work in it. We've had a number of conversations with government agencies, including APHIS, around the issues.

And so we're anxious to step up what we can do to be of help. And we certainly will be participating in this

process. To be able to carve out adventitious presence because it is so critical, and to be able to move on that in a potentially separate track or accelerated, whichever that might be phrased. And we're trying to think ourselves creatively how you do that, because we know it's not easy.

We think that potentially a way in which we might approach this would be from an importation point of view, in that we're just as concerned with products that enter this country that might have trace amounts of unapproved varieties. And so it seems to us that we've got to be as concerned about it from what may be coming into the United States, as well as what's going out. Or what we're using domestically in our --

And so I'd just be curious in saying you may want to do this, as well. If there's any thinking going on along this line, if there's another way in which maybe we can think about approaching this. But I don't think we can overstate to you how important it is that we come up with a science-based approach to adventitious presence, just as soon as we can.

MR. ABRAMSON: We actually looked at a number of publicly-available databases, one maintained by the EU, which indicates very clearly that there are thousands of field trials being conducted by EU nations of biotechnology to crops. We have also looked at information maintained by

ISAAA, the focus is on developmental work being done in other countries around the world, less developed nations. Found that there is a wide variety of crops that are being developed, biotechnology crops being tested in the developing nations.

But in virtually all of these cases, there is trade between the United States and these countries, whether they be developed or developing. And so it struck us that, while this is not exclusively an APHIS issue, that at least in part it is an APHIS issue. And of course, the issue of adventitious presence is one that has been addressed by the Executive Branch, by all three of the regulatory agencies.

So it struck us that this is something that was a potential source of concern, particularly to the extent that, while we're very comfortable with the oversight just here in the United States, quite frankly, we know a lot less about the level of oversight that's being provided in some of the other countries around the world. So that's why I'm bringing this to your attention today.

MS. BECH: Just a quick comment on that it would be useful for us to hear more of your thoughts around that, especially as it would relate to importation. And any thoughts you have around that would be very useful to hear developed further.

MS. SMITH: And it's worth saying that under our

new regulations, we would be in a position to address fully adventitious presence. At the same time, we recognize that that is further down the road, and we do feel like there are some things we can be doing. And so it is a good time for us to be hearing -- it's another area we're open to hearing thoughtful input about.

MR. PHILLIPS: Yes. Well, we appreciate that. And as I say, we're trying to take each way into it as we can, in terms of how we can use our assisting statutes. And the -- is already there. And we'll continue to further give this area some thought. But we wanted to just bring it to your attention, and just again underscore how important it is that we try to get something moving forward just as quickly as we can. Because the world, I think, is waiting for us. I think we have a responsibility as a country, whether we're an industry or a government, we're looking for leadership. And I think we need, what we all need to be working for is providing that.

MR. ABRAMSON: And just for the record, I think it's important to point out that when we refer to adventitious presence, that there are other interpretations of that term as we go around the world.

MR. PHILLIPS: Yes, right.

MR. ABRAMSON: And so we're referring to it in the same way that the Executive Branch referred to it in the

Federal Registry Notice, as the intermittent low levels of material, bio material from crops that are under development for food or feed use, prior to completion of all applicable regulatory reviews.

We are not referring to material that has completed all applicable regulatory reviews.

MS. BECH: That's a commingling --

MR. ABRAMSON: Yes.

(Pause.)

MR. SCHNEIDER: Just a couple of things. First of all, I commend Davis for trying to put this thing together with Monsanto. As I said, I commend you for trying to put this all together. And I don't envy you trying to compile all the comments you're going to receive.

Having said that, I think one of the issues that will be interesting is how each of the commenters will define something like low risk, because you utilize it in your document around a low-pest risk as you try and develop criteria is one of the considerations I think you'll have to look at very closely. Much as you will a definition around minor, unresolved risk, if you look at a tiered permitting system.

And likewise, supportive of things like the adverse effects issues, I think there is also a watch-out in that, in that there is already an adverse reporting piece

under PIPs, and you want to try to avoid a duplication of the same reports going in more than one direction, because of the implication of doubling the amount of "concern," if that existed out there in the marketplace.

One other thing I'd like to comment on is, as you look at the low-risk exemption for permitting, is there an implication of no regulation if you're looking at commercialization? It's just more of a question as you look at how it's written, because you're saying there might be low-risk exemptions for permits.

MR. TURNER: Which number are you reading from?

MR. SCHNEIDER: Just reading through the document in general. I think the term was low-risk exemption for permitting. Does that have an implication of no approval? And so in our comments, I'm sure we'll try to address those types of things, as well.

MS. SMITH: I think one of the things we've talked about was, where there is a lot of history and there's a lot of science and familiarity with certain traits and certain crops, that we can even look at those and see if there are examples of those that we would determine that we could exempt them from regulation. I think that's how we've looked at that issue.

So we'll be looking at potentially exempting some regulatory appeal if we think that there is enough science

and familiarity with some cases of crops to potentially exempt them from oversight.

But at this point, that's just something that we are initially considering, and we'll have to give a lot more thought to what the criteria will be.

MR. TURNER: I know of two places here where we use exemption. One is number eight, when we're talking about an expedited review, or exemption, or certain -- genetically into your commodities intended for importation.

So in other words, if they're commodities that are like intended for food or feed, and they had those approvals, but didn't necessarily have APHIS approvals. So in that case, for other activities it would still be regulated; it would only be for that importation and commodity use that it would be exempt.

The other one was, right now, as you may know, arabidopsis is exempt from interstate movement or commerce for their own low-risk type of organisms. And they wouldn't be exempt from all regulation, just for the need for those interstate movement permits.

MR. SCHNEIDER: What I'm hearing is the perception that the ex-U.S. regulatory system is as stringent as our own. When you say a quick exemption, or a quick review or an expedited review, there has to be some basis in it for making the assessment that the ex-U.S. regulators have done

a thorough job in the standards that are equivalent to yours. That's almost implied by the statement, which I think it's worth considering as we look at the comments.

MR. TURNER: But the exemption would apply to the importation and use of that going into processing, not widescale cultivation. It would be limited in scope.

And of course, we're just asking the question now is that appropriate.

MS. KOEHLER: If I might, the examples that kind of come to mind, I guess the situations that -- like importing transgenic papaya, which obviously would be grown on the farm in -- that kind of importation. So there may be wide products that didn't make it to this country for food or feed use, not for propagation, that one could envision it would have -- on the environment.

MR. ABRAMSON: I guess the question there is how you link that in with any potential food safety issues, like to be associated with a product that we have not had, our agencies have not had occasion to look at.

MR. PHILLIPS: And I think you're about to see implemented action on the point of view and the trade point of view, and noting what, Cindy, you said in your opening comments, in terms of one of your guiding principles is with an eye toward international and working more with countries. The type of question Russ was raising, I think it gets to

what concerns many of us and those that are in the trade here, and that is getting approvals in countries working together on approvals around the world. And working toward a goal of synchronous approvals, if we can ever get there.

But we were just getting into any thoughts you might have in terms of what some thinking might be in those areas, where you think there might be, where reciprocity might be a possibility with other countries to meet the standards that we've set in this country. Whether or not we can start that without having to go through maybe a complete approval meeting, extradited, or what you're thinking there might be. But really you might want to comment on it for us to consider.

MS. SMITH: I don't know that we have a lot of specific information to share along those lines, but that's the kind of thing that we're open to considering and that we'll be talking about in the coming months. Certainly we have historically valued working with other countries where there are approvals. The Roundup Ready Wheat is an example right now, working very closely with Canada.

But a question of the issue of looking at importing commodities that are not intended for propagation raises that, adds that to the radar screen in terms of an issue for us to be looking at.

So at this point I don't know that we have got

much specific to share, but that we are open to any comments and suggestions along those lines.

MR. ABRAMSON: Certainly the idea of looking at the material for commodities for food or feed processing is again consistent with the approach that a lot of countries will be taking under the biosafety protocol, but is not something that is necessarily in agreement. But yet, as you point out, it is subject still to the risk-based assessments under the biosafety program, also. That's something we will definitely take a look at and consider for purposes of our --

MR. PHILLIPS: I think we probably have exhausted our time we have with you. I think we've pretty much asked you what's been on our minds as we've been doing the provenance.

We again just wanted to say to you that we commend you for taking the time to let those stakeholders in this enterprise come in and have an opportunity to discuss these with you. It's been very helpful in terms of, I think we understand better what some of the attendant questions are, and they will help us as we continue to air our informal comments that will -- So we thank you very much for your time.

MS. SMITH: Okay, and we thank you. As you know, everyone's plates are quite full, but we appreciate your

time and the opportunity to spend it with you today, and look forward to talking with you in the coming months. Thanks.

(Whereupon, at 9:25 a.m., the meeting in the above-entitled matter was adjourned.)

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REPORTER'S CERTIFICATE

CASE TITLE: BIO MEETING
HEARING DATE: February 25, 2004
LOCATION: College Park, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: February 25, 2004

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